K073479

JAN - 9 2008

510(k) Summary

510(k) Summary – KINETIC®-SL Anterior Cervical Plate System

Submitted By:	Life Spine 2401 W. Hassell Road, Suite 1535 Hoffman Estates, IL 60169 Telephone: 847-884-6117 Fax: 847-884-6118
510(k) Contact:	Rebecca Brooks Life Spine 2401 W. Hassell Road, Suite 1535 Hoffman Estates, IL 60169 Telephone: 847-884-6117 Fax: 847-884-6118
Date Prepared:	December 10, 2007
Trade Name:	KINETIC®-SL Anterior Cervical Plate System
Common Name:	Spinal Fixation System
Classification:	Spinal intervertebral body fixation orthosis 21 CFR 888.3060 Class II
Device Product Code:	KWQ
Predicate Device:	KINETIC® Anterior Cervical Plate K062643 Life Spine Anterior Cervical Plate System K070285

Device Description:
The KINETIC®-SL Anterior Cervical Plate System consists of various sizes of anterior cervical bone plates and screws. Components are available in a variety of sizes to fit patient anatomy. All components are manufactured from implant grade titanium alloy 6A1-4V ELI per ASTM F-136. KINETIC®-SL Anterior Cervical Plate System components will be supplied clean and "NON-STERILE".

Intended Use of the Device:

The KINETIC®-SL Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. This system is indicated for use in temporary stabilization of the anterior spine from C2 to T1 during the development of a cervical spinal fusion in patients with:
(1) Degenerative disc disease, DDD (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies);
(2) Spondylolisthesis
(3) Trauma (including fractures or dislocations);
(4) Spinal cord stenosis;
(5) Deformity or curvatures (i.e. kyphosis, lordosis and/or scoliosis);
(6) Tumors;
(7) Pseudarthrosis;
(8) Failed previous fusions.

Nota Bene: This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Substantial Equivalence:
The KINETIC®-SL Anterior Cervical Plate System was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2008

Life Spine
% Ms. Rebecca Brooks
2401 W. Hassell Road
Suite 1535
Hoffman Estates, IL 60169

Re: K073479
Trade/Device Name: KINETIC®-SL Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: December 10, 2007
Received: December 11, 2007

Dear Ms. Brooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Life Spine®

Indications for Use

510(k) number (if known): K073479

Device Name: KINETIC®-SL Anterior Cervical Plate System

The KINETIC®-SL Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. This system is indicated for use in temporary stabilization of the anterior spine from C2 to T1 during the development of a cervical spinal fusion in patients with (1) degenerative disc disease, DDD (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies), (2) spondylolisthesis, (3) trauma (including fractures or dislocations), (4) spinal cord stenosis, (5) deformity or curvatures (i.e. kyphosis, lordosis and/or scoliosis), (6) tumors, (7) pseudarthrosis, (8) failed previous fusions.

Nota Bene: This device system is intended for anterior cervical interverterbral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use _x_ (Part 21 CFR 801 Subpart D)	And/Or	Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Barbara Brecht MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073479